Stratton VA
Research & Development Office
Standard Operating Procedure

Procedural Protocol: Initial and Continuing Education Tracking for the Office of Research & Development (WOC's, Committee Members, Investigators and Staff):

Purpose: Due to the nature of research, the R&D office is continuously adding individuals to its oversight domain. The domain of interest in this procedural description is the initial and continuous education and tracking of new researchers and staff.

Policy: The R&D office will admit and process new research staff in an organized, efficient and prompt manner. The intake of new researchers and staff will be completed collaboratively, with positions assuming specific roles, but with each individual in the team prepared to assist another in completion of the overall task of researcher/staff intake and education tracking. The positions currently identified as having designated roles in the intake and education tracking processes are: Program analysts (2 - Human & SRS&B /IACUC), Program Assistant (1), Budget & Fiscal Assistant (1).

Background: The R&D program has seen consistent and continuous increases in procedural requirements directed from Central Office and other regulatory bodies. Many of these procedural requirements are related to training. Each new individual, whether employed staff, research assistant, principle investigator, etc., are required to complete a specific set of trainings on an ongoing basis. Evidence of the completion of these trainings must be tracked for reporting and notification purposes. The R&D office has responded by creating data tracking tools and practices in order to best meet the requirements in this area.

Definitions:
- **Staff** – any researcher (research assistant, principal investigator, sub investigator, employee participating in or supporting research)
- **PI** – Principal Investigator
- **R&D** – Research and Development
- **Human research** – any research that involves the study of living humans, including biological studies, behavioral studies, record reviews, etc.
- **Bench Science & Animal** – any research that involves the use of animals, and/or the use of chemicals, biologicals and radiation that might have untoward effects on humans, animals or the larger environment
- **WOC** – Without Compensation, staff who work without monetary compensation from the VA
- **IPA** – Intergovernmental Personnel Agreement. This type of agreement requires that the person function under the IPA, also has a WOC appointment. This type of

agreement permits the VA to provide funds to reimburse staffing costs for collaborative work.

- **Research Support or Administrative staff** – this includes the paid staff who operate the Stratton VAMC R&D program, including: ACOS for R&D, AO for R&D, Program Analysts (Research Committee Coordinators), Budget & Fiscal Assistant, Program Support Assistant, Animal Lab Technician/Animal Husbandry Specialist
- **Committee Members** – Committee members can be volunteers, WOC employees, federal employees or Investigators. These individuals have different training requirements based on the committee to which they are appointed. The respective committee coordinator is responsible for the committee member's appointment and training.
- **Master List** – This list includes all staff involved in research, and tracks the trainings, certifications and data points required by the Albany VAMC R&D program.
- **HRPP** – Human Research Protection Program. This refers to one of the major functions of the Albany VAMC R&D program. This program defines the effective oversight and protection of human subjects involved in human research at the Albany VAMC.

Staff Admission and Education Procedure:
Any individual who participates in VA Research must have some form of appointment in the VHA system. Examples of types of appointments are: Without Compensation (WOC), Employee, Medical Resident/Trainee, and Contracted. New staff in research (investigators, support staff, WOC, etc.) enter at different areas of the R&D support program. Once entered into the research program, and their position is defined, tracking of education must continue throughout the individual's term in R&D. The staff admission and procedure is comprised of the entry and admission process and then continuous tracking of education process. Examples of the three primary entry points are:

Responsibilities:
- **Program Analysts** (Research Committee Coordinators):
  When e-mail notification is received from the Program Support Assistant, the Program Analysts will contact the Principle Investigator to inquire about the new WOC applicant.
  - HRPP Coordinator/Human Studies/R&D Facilitator – this position will record and oversee the completion of required training for any staff involved in human research. The trainings/certifications/data tracked by this position are: CITI GCP training, Information Security 201, Education level, type of research engaged in, license eligibility determination, human research assessment, role, type of appointment, identified PI, VetPro expiration date (if applicable), scope of practice, Active status (y/n)
  - SRS&B and IACUC Coordinator & Facilitator – this position will record and oversee the completion of required training for any staff involved in research using animals or using chemicals, devices or radiation that might pose a risk or hazard. The trainings/certifications/data tracked by this position are: CITI

IACUC training, CITI animal specific training, CITI Biosafety training, Information Security 201, Education level, type of research engaged in, license eligibility determination, , role, type of appointment, identified PI, VetPro expiration date (if applicable), scope of practice, Active status (y/n).

- o WOC Renewals: When notification of potential WOC renewal applicants is received from Program Support Assistant, **, the Program Analysts** will review the list and inform the Program Support Assistant, which personnel should be renewed as well as who should be inactivated, including the Budget & Fiscal Assistant on the correspondence to ensure removal from the Master List.

- **Program Support Assistant** – this position will notify the Program Analysts via e-mail the name of the research staff member applying for WOC status and the name of the Principle Investigator. Responsibilities will include: record and oversee the completion of required training for any staff designated as WOC's, and which is directly related to guidelines regulating the hiring and supervision of WOC's. The trainings/certifications/data tracked by this position are: Information Security 201, WOC fingerprints, WOC Attachment A, WOC appointment letter, WOC OF 612, WOC OF 306, IPA agreement, computer access requests, Information Security Awareness and Rules of Behavior and VHA Privacy Policy Training, Education level, type of research engaged in, license eligibility determination, human research assessment, type of appointment, identified PI , VetPro expiration date (if applicable). Once the Program Support Assistant has received all documents listed above and appropriate approvals and clearance by HR, a folder will be initiated for each individual and kept in a file cabinet until the Program Analyst requests the folder. Program Support Assistant will also be responsible for notifying the Program Analysts of any WOC renewals on a monthly basis to ensure that only those personnel that are actively participating in research are being renewed. List will be sent to the Program Analysts prior to the Program Support Assistant's meeting with HR and Credentialing and Privileging.

- **Budget & Fiscal Assistant** - this position will record and oversee the completion of required training for any staff designated as research support staff (see "Definitions" above). Additionally, this position will maintain the Master List (see "Definitions"), by recording the individuals involved in research, and the dates of completion of required trainings and certifications; the Program Analysts will be responsible for providing the folder initiated by the Program Support Assistant along with training certificates, a scope and CV to the Budget & Fiscal Assistant. The Budget & Fiscal Assistant will complete monthly audits of the Master List and provide a monthly report which indicates: training and certifications and data that are due within two months, those that are facing expiration by having less than two months remaining and those that are expired. When notification from Program Analysts regarding inactive WOC personnel is received, the Budget and Fiscal Assistant will remove those personnel identified from the active Master List to the inactive list.

Monitoring / Tracking of Education, Training and Information Collection Processes:

Continuous Tracking of Training: Training will have 3 primary tracking domains: Research Specific Training, WOC Training & Certifications, Employee Mandatory Training. These tracking domains will be followed per the guidelines below:

1) Research Specific Training will be followed by the Program Analysts (Research Committee Coordinators) with the assistance of the monthly audits by the Budget & Fiscal Assistant. The Program Analysts will notify relevant staff of their status and report deficiencies to the relevant R&D committees, the ACOS/R, and the AO/R.

2) WOC Training & Certification will be followed by the Program Assistant, however, once the initial training is completed, the respective committee coordinator / program analysts will monitor research specific training continuously, with the assistance of the monthly audits by the Budget & Fiscal Assistant. The Program Assistant will notify relevant staff of their status and report deficiencies to the relevant R&D committee Program Analysts, the ACOS/R, and the AO/R.

3) Employee Mandatory Training will be tracked by the Budget and Fiscal Assistant. The Budget & Fiscal Assistant will notify relevant staff of their status and report deficiencies to the ACOS/R, and the AO/R.

Training/Certification and Data Collection Mandates for Each Research Staff Classification:

UNIVERSAL TRAINING: In addition to mandated employee training, the Albany VA Medical Center training program requires the following training for ALL staff involved in Research (including Investigators, R&D Committee members, Research Office Staff such as ACOS/R and AO/R. and Research Study Staff):

Information Security 201 for Researchers and

VHA Ethics – "Ethics Most Wanted"

- For employees: http://www.lms.va.gov

- For non-VA employees: https://www.ees-learning.net/librix/loginhtml.asp?v=librix (Go to "Available Courses" and "Search" tab and type "Information Security 201")

Category Specific Training Requirements:

Research Staff generally fall into three (3) categories: Investigator, Committee Member, Administrative Staff. Each category typically includes subcategories. The following list indicates the trainings specific to individuals who fall into any of these three categories (individuals may fall into several categories and should follow the guidelines for each that apply to them):

1. **Investigator:** All staff that fall into this category are required to take the following trainings, and/or certifications and/or submit the following data:
   - Statement of Completed Education
   - Scope of Practice (except physicians)
   - VetPro Credential if applicable (see Station Memo 151 for requirements)

   Investigator with VA Network Computer Access and/or Access to Research data:
   - VA Research Information Security Awareness (This is not the same as "Information Security 201 for Researchers)
     For employees: http://vaww.research.va.gov/resources/data-security/training.cfm or https://www.lms.va.gov/plateau/user/login.jsp
     For WOC appointments / non-VA employees: https://www.ees-learning.net/librix/loginhtml.asp?v=librix (Go to "Available Courses" and "Search" tab and type "Information Security 201"

   - VHA Privacy Training/HIPAA:
     For employees: http://vaww.vhaco.va.gov/privacy/Training.htm
     For WOC appointments / non-VA employees: https://www.ees-learning.net/librix/loginhtml.asp?v=librix (Go to "Available Courses" and "Search" tab and type "VHA Privacy" and three choices will show, use "Web Training")

   Investigator with a WOC appointment (including those on IPA):
   - Fingerprinting
   - WOC Attachment A
   - Appointment/Renewal Letter
   - OF 612
   - OF 306
   - Intellectual Property Agreement
   - SF 85 Sensitive Data

   All Investigators: "Ethics Most Wanted"

   Investigator – Human Research
   - Overview of Good Clinical Practice & Human Subjects Protection: http://www.citiprogram.org/
   - VHA Privacy Training/HIPAA: http://vaww.vhaco.va.gov/privacy/Training.htm

   Investigator – Animal Research
   - CITI IACUC
   - CITI species specific (guinea pig, rats, mice, rabbits)
   - CITI Biosafety

   Investigator – Basic Science
   - CITI Biosafety

2. **Committee Member**

 Institutional Review Board Committee Member
- Overview of Good Clinical Practice & Human Subjects Protection:
   http://www.citiprogram.org/

 Biosafety Committee Member
- CITI Biosafety

 IACUC Committee Member
- CITI IACUC Essential for Committee Members
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(These are not a requirement of the IACUC)

Committee Member (any) with WOC appointment: All staff who fall into this category are required to take the following trainings, and/or certifications and/or submit the following data:
- Fingerprinting
- WOC Attachment A
- Appointment/Renewal Letter
- OF 612
- OF 306
- Intellectual Property Agreement
- SF 85 Sensitive Data
- VetPro Credential if applicable (see Station Memo 151 for requirements)

3. **Research Administrative Staff (Requirements of R&D, not VA employment requirements)**

All staff that fall into this category are required to take the following trainings, and/or certifications and/or submit the following data:
- Statement of Completed Education
- VetPro Credential if applicable (see Station Memo 151 for requirements)
- VHA Ethics Training – "Ethics Most Wanted"
- Overview of Good Clinical Practice & Human Subjects Protection:
   http://www.citiprogram.org/
- VA Research Information Security Awareness
   http://vaww.research.va.gov/resources/data-security/training.cfm or
   https://www.lms.va.gov/plateau/user/login.jsp
- VHA Privacy Training/HIPAA:
   http://vaww.vhaco.va.gov/privacy/Training.htm

* Note: The Institutional Official (IO) and Signatory Officials Training: The Institutional Official and signatory officials on the FWA and VA Addendum are required to take the OHRP FWA on-line training.

Non-Compliance with Education, Training, and Information Gathering Procedures:
The thorough execution, collection and tracking of education, training and information gathering in preparation for and continuation of VA research is one of the most critical mandates of VA Research oversight. Ultimately, the PI of every protocol is responsible for being completely familiar with the details of this standard operation procedure (SOP) and assuring her/his own compliance with it, as well as the investigators and others listed on any protocol under his/her direction. The administrative office of the Albany VAMC R&D program will diligently review the status of training and make every effort to provide notification training deadlines in advance to research staff. However, non-compliance with any education requirement will result in the suspension of relevant protocols. Suspensions will be lifted upon the successful completion of any missing or delinquent training, education information requirements. Repeated incidents of non-compliance may result in the removal of authorization to do research at the Albany VAMC.

HRPP Strategies to Disseminate New Information
New information, training opportunities, new policies and procedures are disseminated to non-researchers, R&D Committee members and research staff in multiple training strategies, some of which are described above. Mail groups for R&D Committee members and alternate members, Investigators, HRPP Officials and research staff have been established and are maintained by the Program Analysts and Program Assistant. New information is forwarded via Outlook with "read confirmation." Hard copies of information are also forwarded to members of the mail groups, as needed. Smaller training modules or segments of information are presented at committee meetings, research staff meetings and may also be sent electronically. Documentation of training is maintained by the R&D administrative staff and summary reports provided to the R&D committee.

Materials Provided To Investigators:

1   Albany VA Medical Center HRPP Policy (link: http://visn2portal/sites/albresearch/_layouts/1033/viewlsts.aspx   )

2   Albany VA Medical Center IRB Operations Manual (link: http://visn2portal/sites/albresearch/_layouts/1033/viewlsts.aspx   )

3   Submission forms, templates and materials required for IRB review (link: http://visn2portal/sites/albresearch/_layouts/1033/viewlsts.aspx   )